# The Coping with Unusual Experiences for Children Study (CUES): a pilot randomised controlled evaluation of the acceptability and potential clinical utility of a cognitive behavioural intervention package for young people aged 8 to 14 years with unusual experiences and emotional symptoms

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*Abstract (250 words)*

Objectives: Healthcare guidelines recommend psychological interventions for childhood unusual experiences that are associated with distress or adverse functional impact (UEDs), based on adult, rather than child-specific, evidence. We report the first randomised controlled evaluation of the acceptability and potential clinical utility of cognitive behavioural therapy for childhood UEDs (CBT-UED).

Design: Pilot randomised controlled trial.

Methods: Participants aged 8-14 years were recruited from referrals to community services for children with emotional/behavioural problems, and screened for self-reported UEDs.

Results: Of around 1,000 referrals over 36 months, 304 (30%) were identified to the research team, 174 (57%) were successfully contacted, 110 (63%) consented to screening, 96 (87%) attended a screening assessment, and 51 (53%) reported UEDs. Forty-nine (96%) consented to randomisation to either CBT-UED (9-12 weekly sessions of 40-50 minutes, adjunctive to usual care, n=24) or treatment-as-usual/waitlist control (TAU/WL, n=25). Childhood internalising emotional symptoms (e.g. feeling 'nervous'/'scared'/'tearful'/'worried'/'sick'; proposed primary outcome), UEDs, depression, anxiety, and childhood psychopathology (secondary outcomes) were measured at baseline, at 12-weeks, and, where therapy was ongoing but incomplete (<12 sessions) at 12-weeks, at end-of-treatment (EOT). Twenty-two CBT-UED participants (92%) attended ≥5 sessions. Forty-four participants (90%) completed 12-week assessments (CBT-UED, n=21/24, 88%; TAU/WL, n=23/25, 92%). Preliminary findings were encouraging for emotional symptoms and UEDs, but otherwise mixed.

Conclusions: Retention, screening, and consent rates were as anticipated; recruitment took longer than planned. Trial procedures were acceptable to young people, their families, and clinicians. Therapy exceeded 12 weeks, but was well-received, with no serious adverse events attributed to participation. Further evaluation is needed.

**Practitioner points**

- Around half of 8-14 year olds in child and adolescent mental health services reported distressing unusual experiences
- An age-adapted cognitive behavioural intervention appears feasible, and safe to deliver, with the potential to augment standard care
- This is a pilot study and further evaluation is needed
- Longer term outcomes should be a focus of future evaluation

*Text: 4962 words*

## INTRODUCTION

Unusual experiences[1] (UEs; perceiving or believing things that others find unreal) are commonly self-reported by children in the general population (average prevalence 15%, range 5% to 95%; Kelleher et al., 2012). In around 20% of cases (van Os and Reininghaus, 2016), UEs are persistent, and associated with distress, emotional and behavioural problems and functional impairment (UEDs). UEDs have been argued to be increasingly specific predictors of progression to an 'at-risk mental state' from around fourteen years, indicating specialist intervention aiming to prevent transition to clinical psychosis, although there is debate about the degree of specificity, and need for a broader scope of treatment (Schmidt et al., 2015; Schulze-Lutter et al., 2015; van Os and Guloksuz, 2017). Intervention within general Child and Adolescent Mental Health Services (CAMHS) is recommended for under fourteens seeking help for UEDs, including cognitive behavioural therapy (CBT) to address associated difficulties with mood and functioning (United Kingdom National Institute for Health and Care Excellence, UK NICE, 2013; Schmidt et al., 2015). As younger children with UEs share biopsychosocial features with older adolescents in clinical high risk services, and adults with psychosis (Laurens and Cullen, 2016; Zavos et al., 2014), there is potential for very early intervention, targeting vulnerability factors to reduce future at-risk presentations (Poulton et al., 2014). However, evidence for interventions to date draws primarily on work with adults, rather than exclusively under eighteens. Pilot work shows that offering psychological interventions to younger children with UEDs, to reduce current distress, functional impairment, and, potentially, future mental health risk, is acceptable to children and parents, and may improve current wellbeing (Maddox et al., 2013).

*Footnote: [1]We use the term unusual experiences as young people and parents indicated in consultation prior to the study that they prefer this to 'psychotic' or 'psychotic-like' experiences.*

Later work has underlined the importance of careful adaptation for children: a recent trial showed that adult-oriented CBT for psychosis (CBTp) may be inferior to non-specific support for those at the younger extreme of at-risk service intakes (Stain et al., 2016).

In the current study, we set out to pilot a novel intervention designed for young people (8-14 years) with UEDs (CBT-UED), delivered in addition to usual care, and compared, in a randomised controlled design, to treatment as usual (TAU). The aim was to test whether CBT-UED was a feasible, safe, and potentially helpful addition to TAU, that could be evaluated in UK National Health Service CAMHS.

## METHOD

### *Participants*

Participants aged 8-14 years were recruited to the Coping with Unusual Experiences Study (CUES, ISRCTN 13766770) from referrals to community CAMHS for young people with emotional and behavioral problems that did not usually reach criteria for formal psychiatric diagnosis. We recruited 'clinically-referred', rather than 'help-seeking' children, as, at this age, help is usually sought by parents or schools. The study comprised a baseline screening and assessment phase, with a second phase of participation in the trial offered only to young people meeting screening criteria; that is, those reporting a UE with emotional symptoms in the borderline or clinical range, assessed by the Strengths and Difficulties Questionnaire (SDQ, Goodman, 2001). Service clinicians routinely triaged new referrals: those requiring specialist treatment for a severe mental illness, a specific clinical disorder, or a neurological condition were referred on, and those requiring urgent care were seen immediately. Non-urgent, appropriate referrals were placed on a waiting list for further assessment and treatment, and sent information about the study. We excluded from screening and baseline

assessment only participants who: i) required specialist services (on subsequent assessment); ii) had insufficient written or spoken English ability to complete assessments; or iii) were likely to move away from the local area over the next six months, and thus not be able to complete participation in the trial.

### *Measures*

*Demographic and developmental characteristics*

Age, gender, ethnicity, developmental history (speech/motor delay or current motor problem, Laurens et al., 2007), and family history of mental illness were reported by primary caregivers. Ethnicity was coded dichotomously (BME: any black or minority ethnic group; non-BME: white British or Irish). General intelligence (IQ) was approximated from British Picture Vocabulary Scale standardised scores (BPVS II, Dunn, Dunn, Whetton, & Burley, 1997).

*Strengths and Difficulties Questionnaire (SDQ, Goodman, 2001)*

We used a self-report SDQ, suitable for screening 8-17 year olds for internalising and externalising emotional and behavioural difficulties characteristic of childhood (Goodman, Meltzer and Bailey, 1998; Muris, Meesers and van den Berg, 2003; Goodman, Lamping & Ploubidis, 2010). Four subscales, each of five items rated 0 (not true), 1 (somewhat true) or 2 (certainly true), assess internalising (Emotional Symptoms, Peer Relationship Problems) and externalising (Hyperactivity/Inattention, Conduct Problems) problems. Higher scores indicate greater difficulty. Subscale scores (0-10) combine to form a Total Difficulties score (0-40), assessing general childhood psychopathology. Five items, excluded from the total score, assess Prosocial Behaviour. The Emotional Symptoms subscale (SDQ-ESS, proposed primary outcome) measures symptoms (such as feeling ‘nervous’, ’scared’, ’tearful’,

'worried', 'sick') associated with low mood and anxiety. Borderline or clinical scoring (≥6) at baseline was a screening criterion for study inclusion, and objective justification for offering therapy. Reliable change (i.e. of greater magnitude than the expected measurement error of the instrument, Jacobsen and Truax, 1998) was calculated using the population standard deviation (SD) of 2.1 (Goodman, 2001); improvement to a score <6 was taken as clinically significant change. General childhood psychopathology (SDQ-Total Difficulties, including SDQ-ESS) was a secondary outcome.

*Unusual Experiences Questionnaire (UEQ, Laurens et al., 2007; 2012; Ames et al., 2014)*

This nine-item, self-report questionnaire assesses unusual perceptions and ideas, incorporating five items adapted from the Diagnostic Interview Schedule for Children (DIS-C; Costello, Edelbrock, Kalas, Kessler, & Klaric, 1985) with good internal consistency and validity (Laurens et al., 2012). Items are endorsed on a three-point *Conviction* scale: 0 (not true); 1 (somewhat true); 2 (certainly true). We used an adapted version (Ames et al., 2014) so that endorsed UEs were also rated for *Frequency* over the past two weeks: 0 (not at all); 1 (only once); 2 (2-4 times); 3 (5+ times); *Distress* ('How much has it upset you?') and adverse functional *Impact* ('How much has it made things hard at home or school?'), both rated: 0 (not at all); 1 (only a little); 2 (quite a lot); 3 (a great deal). Item totals (ratings across dimensions of conviction, frequency, distress, and impact: range 0-11), were summed to create a total severity score, and, by selecting only those items where distress or impact was rated >0, a total UED-severity score. Dimension ratings were summed across items to create total conviction (0-18), frequency (0-27), and combined distress/impact (0-54) scores (Ruffell et al., 2015). Secondary UE outcomes for this study comprised: the number of UEs endorsed as somewhat or certainly true (UE-number, 0-9); the number of UEs endorsed with distress/adverse impact >0 (UED-number, 0-9); UE-frequency (total frequency dimension

scores, 0-27); UE-D&I (combined distress/impact dimension scores (0-54); and UED-severity (0-99). Higher scores indicated greater severity. Endorsing any UE as somewhat or certainly true (UE-number≥1) was the second screening criterion for trial inclusion.

*Short Mood and Feelings Questionnaire (SMFQ; Angold et al., 1995)*

The 13-item SMFQ provided a secondary measure of childhood depression, more detailed and specific than the SDQ-ESS. Symptom presence over two weeks is self-rated 0 (not true), 1 (sometimes true), or 2 (true), with a cut-off of ≥8. Convergent validity, sensitivity and specificity are good (Angold et al., 1995).

*Spence Children's Anxiety Scale (SCAS, Spence, 1998)*

The 44-item SCAS provided a secondary, detailed measure of childhood anxiety. Symptoms of generalized anxiety, panic/agoraphobia, social phobia, separation anxiety, obsessive compulsive disorder, physical injury fears, plus six unscored filler items, are self-rated for frequency: 0 (never); 1 (sometimes); 2 (often); or 3 (always). The SCAS is validated in 8-15 year olds; normative mean score across gender and age ranges is 27.4 (SD 16.5); scores of 40+ are considered to be in the clinical range and represent the most anxious 16% of the population (Spence, Barrett & Turner, 2003; Essau et al., 2011).

***Study design***

Participants were randomly allocated, in a 1:1 ratio, to one of two arms, receiving the CUES intervention immediately (CBT-UED) or after 12 weeks (TAU/WL). Randomisation was carried out by the Clinical Trials Unit of King's College London, employing blocks of randomly varying size, stratified by gender. Usual CAMHS treatment continued irrespective of allocation, without any interference from the research team, and was documented for all

participants. We calculated the sample size needed to estimate 95% confidence intervals (CIs) with a margin of error (ME) of +/- 10% for three key trial parameters: retention rate once recruited (estimated 80%); rate of positive screens (estimated 50%); and rate of consent to screening (estimated 50% of those approached). A sample of n=60 eligible participants was required to estimate retention rates, indicating a need to screen n=120 (95% CI, ME +/- 9%), and to approach n=240 (95% CI, ME +/- 6%). Sample size recommendations for estimation of variance range from 24 to 50 participants (Julious, 2005; Sim & Lewis, 2012).

***Procedure***

The study was approved by the London-Hampstead Committee of the United Kingdom National Research Ethics Service (ref. 11/LO/0023), and conducted in accordance with the Declaration of Helsinki (World Medical Association, 2013). Study information packs explaining the two parts of the study (baseline assessment/screening, followed by the treatment evaluation for young people with UEDs) were mailed to parents, with an age-adapted young person's version and assent form. A trained researcher explained the study to families who expressed interest in participating, and sought parental consent and child assent. Consented participants completed screening (UEs and emotional symptoms), and baseline (depression, anxiety and childhood psychopathology) assessments, at their school, home, or CAMHS clinic depending on convenience for the family. Children used a bespoke online survey (SelectSurvey.NET 2.8.5), with researcher support as needed; parents completed paper questionnaires. Young people meeting screening criteria (UE-number ≥1; SDQ-ESS ≥6) were invited to participate in the randomised controlled trial (RCT). Post-treatment measures were completed at 12-weeks, irrespective of therapy completion. After 12-weeks, the TAU/WL participants were offered therapy. All participants completing therapy were re-assessed four weeks after their final therapy session ('1-month post-therapy'). At the request

of participating services, families who agreed to future contact were re-contacted for an opportunistic uncontrolled follow-up, one to four years after their baseline assessment ('1-4 year follow-up'), at which the SDQ and UEQ were re-administered. The trial was registered retrospectively (statutory registration of pilot studies was introduced after study commencement) but the design was unchanged from the funding application and registration preceded completion of recruitment, data-collection and analysis. The trial protocol is available upon request from the authors; the CONSORT checklist is included in Appendix A.

### *Intervention*

The CBT-UED intervention comprised 9-12 individual sessions, each of 40-50 minutes duration, usually delivered weekly. Therapy was adapted from adult CBTp interventions, drawing on pre-pilot work and both young person and parent consultation (Maddox et al., 2013; Browning et al., 2013; Table 1). The intervention was manualised, with sessional plans, interactivities, between-session tasks, and co-produced, developmentally appropriate handouts. Therapy was delivered by the manual co-creator, KB, an experienced CAMHS nurse with postgraduate qualifications in CBT, and CBTp. Supervision was provided by SB, the lead author of the manual and CAMHS consultant clinician, trainer and trial therapist. Therapy adherence was rated by KB and SB using a sessional activity checklist. Four raters, independent of therapy delivery, assessed 16 sessions (of 140 completed with 21 participants, 11%), using a comprehensive checklist of CBT and CBTp activities. Raters agreed on 88% of competence ratings and 90% of presence ratings, with no session rated as not competent (Nasseri, 2015).

*Table 1 here*

***Statistical analysis***

Analyses were performed using the Statistical Package for the Social Sciences (SPSS, v.22, IBM, 2013) and STATA version 14.0 (Statacorp, 2015). Baseline characteristics were summarized using descriptive statistics. Acceptability of trial procedures was examined using proportions and 95% CIs (consent to screening, target 50%; eligibility, target 50% of those screened; retention, target ≥ 80%; we anticipated a recruitment rate of 3 participants/month from 28 new referrals). Acceptability of treatment was judged by uptake, sessions attended, and retention. Potential helpfulness was judged by the proportion of young people showing reliable or clinically significant improvement on the SDQ-ESS in the intervention group compared to the control group, with Odds Ratios (ORs) transformed to between group effects (d) using the Logit method. ORs were also calculated for other categorical outcomes (meeting trial screening criteria; UE-number ≥1/<1; UED-number ≥1/<1). Emphasis was placed on CIs of effect size estimates, rather than hypothesis testing, allowing for exploration of imprecision around effect sizes. As therapy was ongoing but incomplete (<12 sessions) for most participants at 12-weeks, we created, post-hoc, an end-of-treatment (EOT) outcome, using 1-month post-therapy scores for young people who were allocated to, but had not completed, therapy at 12-weeks, and the 12-week score for all other young people.

*Missing data*

Scores for multi-item measures were classified as missing data if three or more items were incomplete, and prorated otherwise. One TAU/WL participant withdrew consent to use their data. One TAU/WL and three CBT-UED participants missed the 12-week assessment. We analysed proposed primary SDQ-ESS and secondary UE scores under the missing at random (MAR) assumption (White, Horton, Carpenter, & Pocock, 2011). Predictors of missingness were identified using a series of random intercept logistic regression analyses. We

investigated age, gender, ethnicity, IQ, baseline SDQ-ESS, UED-severity, and SDQ-Total, allocation, and time of assessment (baseline or 12-weeks). For the 1-4 year follow-up, we additionally investigated age at follow-up and length of time from randomisation to follow-up. None of the variables significantly predicted missing data at 12-weeks or follow-up (z scores all < 1.8, p values all > 0.08); therefore, we assume missing completely at random (MCAR) and no additional variables were controlled in subsequent analyses.

*Treatment effect estimation*

Non-categorical clinical outcomes were analysed on an intention-to-treat basis using a random intercept logistic regression analysis, comparing outcomes at 12-weeks and EOT between the CBT-UED and TAU/WL conditions, with baseline outcome measures as a covariate. The same analyses were repeated for the proposed primary outcome (SDQ-ESS) and for each secondary outcome variable (UE-number; UED-number; UE-frequency; UE-D&I; UED-severity; SDQ-Total; depression; anxiety). Between-group treatment effects (d) were also calculated as the difference in mean change between groups, divided by SD, adjusted for the degree of association between pre and post scores. To estimate sample size for future studies, 95% CIs for treatment effects were recalculated for key outcomes, using the upper limit of the 80% CI as a robust estimate of variance.

*Additional analyses*

As this was a pilot evaluation of a novel intervention, changes in primary and secondary outcomes within each allocation group were also examined for each time point, using McNemar tests for categorical variables and, for continuous variables, paired t-tests with Cohen's d calculated as the difference between the pre- and post-treatment means divided by

the SD of the difference, adjusted for the correlation between pre- and post-treatment scores. Again, 95% CIs for estimation of pre-post effects are reported.

Potential predictors of therapy completion (age, gender, ethnicity, IQ, allocation, and SDQ-ESS, UED-severity, and SDQ-Total scores, each at baseline and 12-weeks) were examined using a series of random intercept logistic regression analyses.

For the 1-4 year follow-up, Pearson correlations were employed to examine the association with outcomes of participant age at follow-up and time from randomisation to follow-up, calculated with and without adjustment for initial allocation. To assess durability of changes following treatment, pre-post effect sizes were estimated for within-participant change from baseline to 1-month post-therapy and to 1-4 year follow-up (durability indicated by comparable changes), and from 1-month post-therapy to 1-4 year follow-up (durability indicated by the absence of deterioration).

## RESULTS

### *Participant flow*

The CUES project recruited from May 2011 to April 2014; follow-ups were completed by January 2016. Participant flow is illustrated in Figure 1. Of around 1,000 expected referrals to the service (average 28/month over 36 months), 304 (30%; 95% CI: 27% to 33%) were identified to the research team as potential contacts, 174 (57%, 95% CI: 51% to 63%) met age criteria and were successfully contacted, and 110 (63%, 95% CI: 59% to 67%) consented to participate. Ninety-six completed screening (55% of those contacted, 95% CI: 48% to 62% [target: 50%]; 87% of those consenting, 95% CI: 81% to 93%). Of 51 meeting screening criteria (53%, 95% CI: 43% to 63% [target: 50%]), all but two (96%; 95% CI: 91% to 100%)

agreed to randomisation (24 to CBT-UED; 25 to TAU/WL). Actual recruitment rates were slower than estimated, necessitating an extension to recruitment (2.7/month recruitment to screening [target: 6/month]; 1.4/month meeting screening criteria [target: 3/month]). Forty-four participants completed 12-week outcomes (90% (95% CI: 82% to 98%); 21/24 CBT-UED, 23/25 TAU/WL).

*Figure 1 here*

*Baseline demographic and clinical characteristics*

Young people meeting screening criteria had higher scores on all outcome measures, and lower IQ scores than those not meeting screening criteria, with mean SDQ-Total, anxiety and depression scores in the clinical range (Table 2). Screening positive was not associated with age, ethnic background, family/parental history of mental ill-health, or history of developmental problems. Young people not meeting screening criteria were more likely to be male. Amongst trial participants, SDQ-Total ($r=0.4$, $p=0.008$, $n=48$) and depression ($r=0.4$, $p=0.01$, $n=46$) scores were higher in older children. Girls, compared to boys, reported more depression ($r=0.4$, $p=0.02$, $n=46$). Lower IQ was moderately associated with higher SDQ-ESS, UE-frequency, UE-D&I and anxiety scores (r values 0.3 to 0.5, p values $< 0.05$). All other r values were $< 0.3$, $p>0.05$.

*Table 2 here*

*Adverse events*

We classified as a potential adverse event any deterioration in the young person's mental health or welfare, that was noted by the young person, family/responsible adult, clinical team or study team. Any such event judged by any of these parties as related to study participation was considered to be an adverse event, and was rated for severity according to the degree of

adverse impact upon the young person. Three potential adverse events were identified, all by the study team. Two occurred in the TAU/WL group: a non-fatal overdose, and an identified social care need, resulting in withdrawal of consent. One occurred in the CBT-UED group: readmission to psychiatric hospital following relapse of a pre-existing, relapsing mental health condition. No event was considered by the young person, family, treating team, or study team to represent a change in presentation arising because of study participation (although the identification of the social care need occurred because of participation, the need itself did not). In each case, the study team was closely involved in facilitating appropriate care.

*Therapy completion at 12-weeks*

Of the 21 CBT-UED participants completing a 12-week assessment, four (19%, 95% CI: 10% to 28%) elected to discontinue therapy early after 5-7 sessions. One more attended only five sessions over 12 weeks, and was referred by the treating team to a specialist service after the 12-week assessment. The remaining 16 had only completed just over half of their therapy sessions by 12-weeks (mean 7.1, SD 2.0; range 4-11 sessions); 60% (range 30% to 90%) of the total received by therapy completion (mean 11.9, SD 1.4, range 10-14 sessions). Of the three participants not completing a 12-week assessment, one was lost to follow-up before starting therapy, one received two sessions before being admitted to hospital and withdrawing from the study, and one received six sessions, before being transferred to a specialist service and subsequently lost to follow-up.

*Therapy uptake after waitlist control*

Of the 23 TAU/WL participants offered therapy after completing the 12-week assessment, 19 took up the offer and four declined. Of those taking up the offer, 17/19 engaged in a full

course of therapy (mean 11.2, SD 1.7, range 8-14 sessions); one started, but was referred to another service after seven sessions and was then lost to follow-up; and one attended one session only and then dropped out.

*Predictors of therapy completion*

Age, gender, ethnicity, IQ, allocation, and SDQ-ESS, UED-severity, and SDQ-Total scores at baseline and at 12-weeks were investigated as potential predictors of therapy non-completion using a series of random intercept logistic regression analyses. Only SDQ-Total at baseline was a significant predictor (Coefficient = 0.2, p=0.02, 95% CI: 0.03 to 0.4, otherwise z scores all < 1.1 p values all > 0.3). Post-hoc examination revealed significant subscale differences only for Conduct Problems (non-completers mean 4.8, SD 2.3, n=15; completers mean 3.0, SD 1.9, n=33; t=2.8, df=46, p=0.007; else, t values < 1.7, p values > 0.1).

*Usual care*

Usual care was not documented for the five young people who withdrew consent or were lost to follow-up; no data was available for one further TAU/WL participant. For the remaining participants (n=21 CBT-UED, n=22 TAU/WL) usual care ranged from no contact (n=8 CBT-UED, n=9 TAU/WL), through one-off assessment/review without intervention (n=3 CBT-UED; n=3 TAU/WL), to regular meetings with specialist CAMHS practitioners for support tailored to referral problems (n=10 CBT-UED; n=10 TAU/WL).

*Does the CBT-UED therapy show potential to improve outcomes compared to usual care?*

The proportion of participants showing reliable change (exceeding expected measurement error, Jacobsen and Truax, 1998) and clinically significant change (to a non-clinical score, <6) on the SDQ-ESS at 12-weeks and EOT was compared between the CBT-UED group and

the TAU/WL group, with ORs transformed to d values using the Logit method. No participant showed reliable deterioration. A non-significantly higher proportion of the CBT-UED group showed reliable improvement (29% CBT-UED; 13% TAU/WL, d(Logit)=0.6, 95% confidence interval [CI]: -0.02 to 1.2) and clinically significant improvement (from above to below the borderline/clinical threshold; 52% CBT-UED; 39% TAU/WL, d(Logit)=0.3, 95% CI: -0.3 to 0.9). Allocation groups did not differ significantly on any categorical outcome at either 12-weeks or EOT ($\chi 2$ values < 1.0 (df=1), p values > 0.5), ORs are shown in Table 3.

Continuous outcomes were analysed on an intention-to-treat basis using a series of random intercept logistic regression analyses, comparing each outcome firstly at 12-weeks, then at EOT, between the CBT-UED and TAU/WL conditions, with baseline score as a covariate. Treatment effects (lower score, better outcome) were very small at 12-weeks for the proposed primary SDQ-ESS outcome (Coeff. = -0.1, p=0.9, 95% CI: -1.5 to 1.3), and for all secondary UE and other outcomes (z scores all < 1.0, p values all > 0.3). At EOT, treatment effects were larger: no significant differences were found for SDQ-ESS (Coeff.=-0.4, p=0.6, 95% CI: -1.7 to 0.9), but there were group differences on the secondary UE measures at EOT, reaching statistical significance for UED-severity (Coeff.=-6.8, p=0.04, 95% CI: -13.3 to -0.2), with a trend for UED-number (Coeff. -1.0, p=0.07, 95% CI: -2.2 to 0.07) and UE-D&I (Coeff.=-2.6, p=0.07, 95% CI: -5.4 to 0.3; otherwise z scores all < 1.3, p values all > 0.2). Group means and between group treatment effects (d) are shown in Table 4.

Within group, pre-post changes are also shown in Tables 3 and 4, showing no deterioration in either group, and overall small pre-post changes within the TAU/WL group (on SDQ-ESS,

two UE measures, and SDQ-Total [t values >2.0, p<0.05], and all categorical outcomes, but not UE-frequency, UE-number or UED-number, anxiety or depression [t values < 0.2, p > 0.05]), and larger pre-post changes within the CBT-UED group, particularly at EOT (significant t values > 2.5, p values < 0.05; else t values < 2.5, p values > 0.05), except on depression, which did not change (t value < 1.0, p value > 0.4).

*Tables 3 and 4 here*

*Do changes persist?*

Young people (n=19) completed 1-4 year follow-up assessments at a mean of 2.5 years (SD 0.9, range 1.3-3.8) after randomization. Longer time to follow-up was associated with fewer UEs (r=-0.6, p=0.01) and fewer UEDs (r=-0.6, p=0.01), irrespective of controlling for initial allocation (otherwise r values ranged from 0.1 to -0.3, p values > 0.1). Mean age at follow-up was 14.1 years (SD 2.3, range 10.2 to 18.7). Age was unrelated to any outcome score, irrespective of initial allocation (r values ≤ 0.3, p values > 0.1). Effect size estimates comparing scores from baseline to 1-month post-therapy to 1-4 year follow-up, showed small deteriorations from the 1-month post-therapy assessment, and persisting improvement compared to baseline. For categorical outcomes, by 1-4 year follow-up, although UE/UED rates had increased, associated SDQ-ESS scores were not in the clinical range (Table 5).

*Table 5 here*

*Variance estimates for future power analyses*

Treatment effects and 95% CIs were recalculated for the SDQ-ESS categorical outcomes (reliable improvement and clinically significant improvement) using the upper limit of the

80% CI for the standard error of ORs, transformed to d values using the Logit method, and for the SDQ-ESS and UED-severity baseline and EOT mean scores, using the bootstrapped upper 80% CI limit for the standard deviation. Treatment effects ranged from d=0.2 to 1.3 for SDQ-ESS reliable improvement; from d=0.3 to 0.8 for SDQ-ESS clinically significant improvement; from d=-0.3 to 0.9 for SDQ-ESS mean score; and from d=0.1 to 1.1 for UED-severity mean score. These estimates suggest sample sizes from n=176 to in excess of 500 participants to reliably (with 95% power, $\alpha$ =0.05) evaluate between-group change in SDQ-ESS, and of n=110 to evaluate change in UED-severity.

## DISCUSSION

We evaluated whether our novel CBT-UED intervention, adapted specially for children, was feasible, safe, and a potentially helpful addition to usual community CAMHS care. Following treatment recommendations, clinical distress (emotional symptoms) was the proposed primary outcome. We also measured change in unusual experiences, employing a range of indices to determine the most useful measurement for clinical purposes and potential future evaluation.

The study was well-received by services, parents and young people. Screening and assessment procedures were developmentally appropriate, with good completion in our frontline setting. However, assessors needed skills in engagement, and in managing the challenge of balancing interactivity/play with task-focused activity. The two-stage design was acceptable to participants and their families. The randomisation procedure was unproblematic. The CBT-UED intervention was feasible to implement and positively received across the board. No adverse events were causally attributed to the therapy or assessments. Retention at 12-weeks was good. Over half of participants and families were uncontactable for the opportunistic 1-4 year follow-up, possibly reflecting our mobile inner-

city population. Higher levels of childhood psychopathology, and potentially particularly Conduct Problems, were associated with therapy non-completion. Further investigation of this is needed: alternative approaches may better suit externalising problems.

Screening suggested that around half of CAMHS referrals have a UE with clinical/borderline distress on the SDQ-ESS and could be offered intervention. However, as treatment guidance specifies self-reported distress, without clinical criteria, rates may in practice be higher: all but one trial participant self-reported distress/impact on the UEQ but 19 young people (17% of those screened) reported a UED with SDQ-ESS<6, and were excluded. Selection and screening methods may therefore require further investigation to ensure the target population is accessed. While the proportion of young people and their families agreeing to screening and meeting eligibility criteria was within the target range, the recruitment rate was less than half of that predicted, with only a third of referrals put forward to the research team, and only half of these contactable. Clinician feedback indicated that, rather than asking all referrals about the research, and two thirds having refused contact, they were inadvertently pre-selecting potentially suitable participants to ask. Routine screening in services may circumvent this difficulty, and facilitate investigation of barriers to access.

Therapy was well-delivered, as expected from expert clinicians, but the time needed to complete therapy exceeded 12 weeks in nearly every case, and one or two extra sessions (14 sessions in total) were required for several cases to cover the manualised therapy content. The additional input appeared to be useful as outcomes improved slightly between 12-weeks and EOT, and may reflect the greater complexity of difficulties in this CAMHS setting compared to a general population case series. A longer course of therapy, and an additional month to complete therapy, would improve future studies in clinical contexts.

The range of estimated treatment effects generally slightly favoured the CBT-UED group, for all outcomes except depression and SDQ-Total, and particularly for UE outcomes. There was no suggestion that the CBT-UED intervention caused harm, and some positive change with TAU/WL. Between group SDQ-ESS differences were smaller than anticipated (d=0.3 to 0.6), indicating a substantially larger sample size for a future, similar analysis with adequate power to detect between-group differences. UED between group differences were larger, but baseline scores differed markedly, despite random allocation, with unknown impact on the likelihood and magnitude of change. Findings suggest that CBT-UED may have most potential to augment usual CAMHS care by improving UE specific outcomes, rather than general psychopathology. Of the UE outcomes, UED-severity changed most consistently, and, pending replication, may be an appropriate primary outcome in future studies, particularly given its role in influencing future trajectories (Lin et al., 2011). In their feedback, young people particularly noted the helpfulness of normalising information about coping with UEDs, and suggested that this could usefully be provided from an early age in schools, as they wished they had understood their own experiences sooner.

The gains made during any treatment were somewhat durable: only a third of participants still met screening criteria at the 1-month post-therapy and 1-4 year follow-ups, with small, non-significant between group differences at EOT favouring CBT-UED (43% vs. 52%). While UEs and UEDs had partially returned by follow-up, reductions in severity and clinical distress persisted, potentially reflecting more adaptive ways of responding.

*Limitations*

Several issues should be considered in interpreting findings. The study was a pilot, not powered to detect treatment effects, and multiple comparisons were conducted without correction. We recruited from a single inner-city UK NHS Trust: findings may be context-specific. Longer term follow-up assessments were uncontrolled, so cannot inform estimates of treatment effects, and all assessments were conducted unblinded, potentially inflating effects. Only half of participants could be contacted for the opportunistic 1-4 year follow-up, potentially biasing the sample, although attendance was not associated with baseline demographic or clinical variables. Alternative follow-up methods, that do not require contacting families (e.g. primary care records), could mitigate bias in future studies, with provision made to obtain the young person's ongoing consent (in addition to their original assent to parental consent) once they reach 16 years.

*Conclusions*

Around half of children presenting to CAMHS with emotional and behavioural difficulties may also have a UED warranting an offer of intervention. Our findings indicate that while routine care has a small impact in improving UEDs, a novel therapy specifically targeting these experiences in childhood was feasible and safe to deliver, and may augment standard care. Further evaluation is required. Key issues to consider in future research are the selection criteria for participants; the choice of primary outcome and consequent sample size implications; the time frame to deliver therapy; and the logistics of following up young people living in an inner city setting over a longer time period.

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**Table 1:** Intervention content overview by session

| Session number | Content |
|---|---|
| **1. Engagement & Assessment** | Rapport, overview, giving folders/pens and paper. Start assessment. Benefits of exercise, diet and sleep. |
| **2. Assessment & Goal Setting** | Rapport; problems & goals; Discussion of PLE's, anxiety & beliefs. Introduce a psychological model - why me, why now, why still, what helps? |
| **3. Psychoeducation** | What is anxiety/worry/anger? Anxious or worrying feelings are horrid but can't hurt us. Personal triggers, CBT model |
| **4. Coping strategies** | Activity scheduling; distraction; relaxation training: there are things I can do myself to manage my worry. Cognitive coping strategies. |
| **5. Problem Solving** | Traffic lights system (stop, think then do). Looking back (reviewing how it went) can help me to leap forward. General and personalised examples. |
| **6. Top Brain Training** | Understanding PLEs, normalising & psychoeducation; coping strategies; role of cognitive biases |
| **7. Test it out** | Behavioural experiments |
| **8. Set-backs** | Review model; normalising blips – everyone has bad days; identify future difficult situations/times - what signs to look out for; strategies. |
| **9. Ending** | Review learning points and ending certificate |

Figure 1: CONSORT diagram illustrating participant flow through the trial

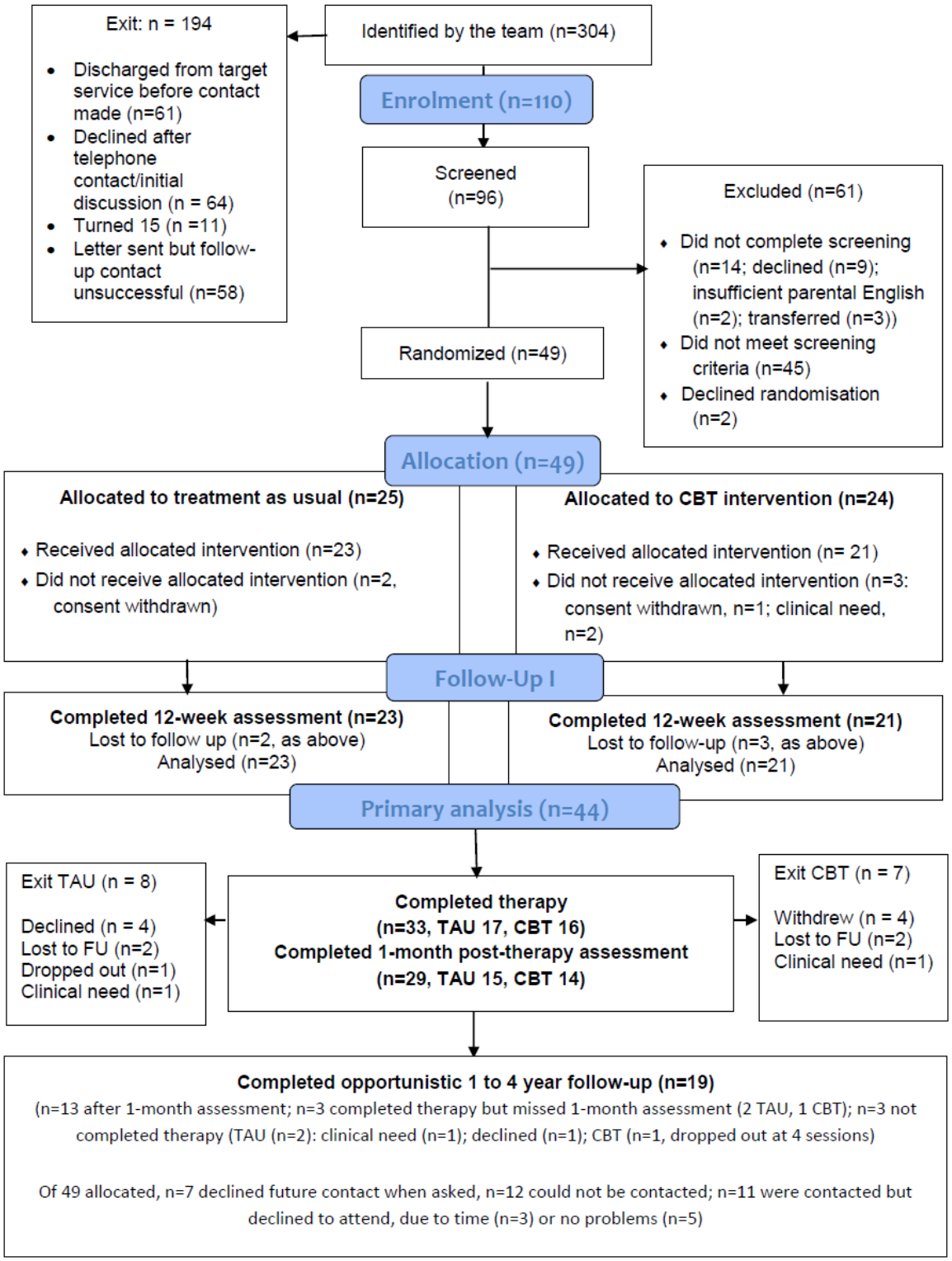

**Table 2.** Demographic and clinical characteristics of participants at baseline.

| Variable | TAU/WL *n = 24*[1] | CBT-UED *n = 24* | Trial total *n = 48*[1] | Non-trial total *n=61* | *Test (trial cf. non-trial)* |
|---|---|---|---|---|---|
| | | **Mean (SD)** | | | ***t, p*** |
| **Age (years)** | 11.8 (2.0)[1] | 11.5 (2.2) | 11.7 (2.1)[1] | 11.6 (1.9) | *t(108)=0.2, NS* |
| **IQ (BPVS)** | 84.7 (13.4) | 89.4 (19.1) | 87.0 (16.5) | 93.8 (14.4)[2] | *t(102)=-2.2** |
| **SDQ-ESS** | 7.0 (1.0) | 7.6 (1.3) | 7.3 (1.2) | 3.4 (2.0)[3] | *t(82.4)=12.0**** |
| **UE-frequency** | 6.7 (3.7) | 9.5 (5.9) | 8.1 (5.1) | 2.8 (4.1)[4] | *t(99)=5.8**** |
| **UE-D&I** | 8.2 (5.7) | 13.6 (9.5) | 10.9 (8.2) | 1.4 (2.8)[4] | *t(56.6)=7.6**** |
| **UED-number** | 3.0 (1.5) | 4.5 (2.4) | 3.8 (2.1) | 0.8 (1.4)[4] | *t(78.5)=8.2**** |
| **UE-number** | 3.8 (2.0) | 5.0 (2.2) | 4.4 (2.2) | 2.0 (2.3)[4] | *t(99)=8.4**** |
| **UED-severity** | 18.2 (10.6) | 29.4 (18.6) | 23.8 (16.0) | 3.9 (7.2)[4] | *t(63.7)=7.9**** |
| **Depression** | 11.7 (5.6) | 12.4 (6.6)[5] | 12.0 (6.0)[6] | 5.3 (4.6)[7] | *t(83.9)=6.1**** |
| **Anxiety** | 44.3 (17.3) | 47.5 (18.0) | 45.9 (17.5) | 26.1 (14.1)[4] | *t(99)=6.3**** |
| **SDQ-Total** | 20.6 (3.6) | 20.9 (6.2) | 20.7 (5.0) | 12.8 (5.7)[3] | *t(97)=7.4**** |
| | | **% (n)** | | | ***$\chi^2$, p*** |
| **Gender** (F:M) | 52%:48% (13:12)[1] | 54%:46% (13:11) | 53%:47% (26:23)[1] | 26%:74% (16:45) | *$\chi^2(1)=8.3$*** |
| **Ethnicity** BME/non-BME | 42%:58% (10:14) | 50%:50% (12:12) | 46%:54% (22:26) | 53%:47% (31/27) | *$\chi^2(1)=0.6$, NS* |
| **SDQ-ESS** Clinical range | 100% (24) | 100% (24) | 100% (48) | 14% (7)[3] | *$\chi^2(1)=74.5$**** |
| **UE** Present | 100% (24) | 100% (24) | 100% (48) | 64% (34)[4] | *$\chi^2(1)=21.2$**** |
| **UED** Present | 100% (24) | 96% (23) | 98% (47) | 36% (19)[4] | *$\chi^2(1)42.8$**** |
| **Family/ Parental MI** | 92%/44% (23/11)[1] | 54%/42% (13/10) | 73%/43% (36/21)[1] | 56%/41% (34/25) | *$\chi^2(2)=4.0$, NS/ $\chi^2(2)=0.05$, NS* |
| **Speech/motor difficulty** | 39% (7)[8] | 35% (6)[9] | 37% (13)[10] | 18% (7)[11] | *$\chi^2(1)=3.1$, NS* |

*Key: TAU/WL: Treatment as usual/waitlist control group; CBT-UED: Cognitive behavioural therapy for unusual experiences with distress intervention group; SD: standard deviation; df: degrees of freedom; IQ: Intelligence Quotient; BPVS = British Picture Vocabulary Scale (Dunn et al., 1997). SDQ: Strengths and Difficulties Questionnaire (Goodman, 2001); ESS: Emotional Symptoms Scale; UE = unusual experience; UE-D&I: Distress and adverse impact associated with UE; UED = unusual experience with distress or adverse impact; BME: Black or minority ethnic: MI: Self-reported mental illness history; [1]n=additional TAU participant (n=25, TAU; 49 trial); [2]n=56; [3]n=51; [4]n=53; [5]n=22; [6]n=46; [7]n=52; [8]n=18; [9]n=17; [10]n=35; [11]n=38; *p<0.05; **p<0.01; ***p<0.001*

**Table 3:** Variability of change in proposed primary and secondary outcomes within and between participant groups.

| | | TAU/WL group (n=23) | | | CBT-UED group (n=21) | | | | | *12-week between groups ES (95% CI)* | *EOT between groups ES (95% CI)* |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Assessment:** | **Baseline Mean (SD)** | **12-week Mean (SD)** | ***Pre-post ES (95% CI)*** | **Baseline Mean (SD)** | **12-week Mean (SD)** | ***Pre-post ES (95% CI)*** | **EOT Mean (SD)** | ***Pre-post ES (95% CI)*** | | |
| *Primary* | **SDQ-ESS** | 7.0 (1.0) | 5.8 (2.0) | *0.5* (-0.1 to 1.1)* | 7.6 (1.2) | 5.9 (2.8) | *0.6** (0.1 to 1.2)* | 5.6 (2.3) | *0.9** (0.3 to 1.5)* | *0.2 (-0.4 to 0.8)* | *0.3 (-0.3 to 0.9)* |
| *Secondary UE* | **UE-frequency** | 6.8 (3.8) | 5.3 (4.9) | *0.4 (0.1 to 0.7)* | 9.0 (6.2) | 6.6 (6.0) | *0.4 (-0.0 to 0.8)* | 5.2 (5.7) | *0.7** (0.3 to 1.2)* | *0.2 (-0.4 to 0.8)* | *0.5 (-0.1 to 1.1)* |
| | **UE-D&I** | 8.2 (5.8) | 5.6 (5.8) | *0.5* (0.1 to 0.9)* | 12.4 (8.7) | 7.0 (7.1) | *0.6* (0.1 to 1.1)* | 4.9 (5.5) | *1.1*** (0.6 to 1.6)* | *0.4 (-0.2 to 1.2)* | *0.8* (0.2 to 1.4)* |
| | **UED-number** | 3.0 (1.5) | 2.3 (2.0) | *0.4 (0.0 to 0.8)* | 4.4 (2.5) | 2.7 (2.3) | *0.6** (0.1 to 1.1)* | 1.9 (2.1) | *1.0*** (0.4 to 1.6)* | *0.5 (-0.1 to 1.1)* | *0.8** (0.2 to 1.4)* |
| | **UE-number** | 3.8 (2.0) | 3.1 (2.2) | *0.4 (0.0 to 0.8)* | 4.9 (2.2) | 3.5 (2.6) | *0.6* (0.1 to 1.1)* | 2.8 (2.5) | *0.8** (0.3 to 1.3)* | *0.3 (-0.3 to 0.9)* | *0.6* (0 to 1.2)* |
| | **UED-severity** | 18.2 (10.8) | 13.1 (13.3) | *0.5* (0.1 to 0.9)* | 27.3 (18.1) | 15.9 (15.6) | *0.7** (0.2 to 1.2)* | 11.2 (13.6) | *1.1*** (0.6 to 1.6)* | *0.5 (-0.1 to 1.1)* | *0.9** (0.3 to 1.5)* |
| *Secondary mood / psychopathology* | **Depression**[1] | 11.7 (5.9) | 10.8 (6.0) | *0.2 (-0.2 to 0.6)* | 11.5 (6.2) | 10.3 (6.6) | *0.2 (-0.3 to 0.7)* | 10.8 (7.1) | *0.1 (-0.4 to 0.6)* | *0.05 (-0.6 to 0.7)* | *-0.03 (-0.7 to 0.6)* |
| | **Anxiety**[2] | 43.4 (17.5) | 38.7 (18.7) | *0.3 (-0.0 to 0.6)* | 47.0 (17.4) | 38.8 (19.1) | *0.4 (-0.1 to 0.9)* | 35.0 (20.2) | *0.7* (0.3 to 1.2)* | *0.2 (-0.4 to 0.8)* | *0.5 (-0.1 to 1.1)* |
| | **SDQ-Total** | 20.8 (3.5) | 17.4 (6.0) | *0.6* (0.1 to 1.1)* | 20.0 (6.3) | 18.1 (7.4) | *0.3 (-0.2 to 0.8)* | 17.6 (6.2) | *0.4* (-0.0 to 0.8)* | *-0.2 (-0.8 to 0.4)* | *-0.2 (-0.8 to 0.4)* |

*Key: TAU/WL: Treatment as usual/waitlist control group; CBT-UED: Cognitive behavioural therapy for unusual experiences with distress intervention group; SD: standard deviation; SDQ: Strengths and Difficulties Questionnaire (Goodman, 2001); ESS: Emotional Symptoms Scale; UE = unusual experience; UE-D&I: Distress and adverse impact associated with UE; UED = unusual experience with distress or adverse impact; [1]n=22, TAU/WL; n=20, CBT-UED); [2]n=22, TAU/WL; n=21, CBT-UED; ES: effect size, Cohen's d, derived from pre-post or between group change mean differences over the common SD; *p<0.05; **p<0.01; ***p<0.001 – significance levels derived from within group paired t-test of pre-post scores or between group independent samples t-test of change scores*

**Table 4:** Variability of change in clinical status outcomes within and between participant groups.

| | **TAU/WL group (n=23)** | | | **CBT-UED group (n=21)** | | | | | ***12-week between groups OR (95% CI)*** | ***EOT between groups OR (95% CI)*** |
|---|---|---|---|---|---|---|---|---|---|---|
| **Assessment:** | **Baseline** | **12-week** | | **Baseline** | **12-week** | | **EOT** | | | |
| | **% (n) (95% CI)** | | ***p*** | **% (n) (95% CI)** | | ***p*** | | ***p*** | | |
| **SDQ-ESS** Reliable change | - | 13% (3) (6% to 20%) | - | - | 29% (6) (19% to 39%) | - | 29% (6) (19% to 39%) | - | *2.7 (0.6 to 12.4)* | *2.7 (0.6 to 12.4)* |
| **SDQ-ESS** Clinical range | 100% (23) | 61% (14) (51% to 71%) | *0.004* | 100% (21) | 48% (10) (37% to 59%) | *0.001* | 48% (10) (37% to 59%) | *0.001* | *1.7 (0.5 to 5.7)* | *1.7 (0.5 to 5.7)* |
| **SCREEN +ve** | 100% (23) | 52% (12) (42% to 62%) | *0.001* | 100% (21) | 48% (10) (37% to 59%) | *0.001* | 43% (9) (32% to 54%) | *<0.001* | *1.2 (0.4 to 3.9)* | *1.4 (0.4 to 4.8)* |
| **UE** Present | 100% (23) | 78% (18) (69% to 87%) | *0.06* | 100% (21) | 81% (17) (72% to 90%) | *0.1* | 76% (16) (67% to 85%) | *0.06* | *0.8 (0.2 to 3.7)* | *1.1 (0.3 to 4.6)* |
| **UED** Present | 100% (23) | 74% (17) (65% to 83%) | *0.03* | 96% (20) (92% to 100%) | 76% (16) (67% to 85%) | *0.1* | 62% (13) (51% to 63%) | *0.02* | *0.9 (0.2 to 3.5)* | *1.7 (0.5 to 6.3)* |

*Key: TAU/WL: Treatment as usual/waitlist control group; CBT-UED: Cognitive behavioural therapy for unusual experiences with distress intervention group; SCREEN+ve: scoring in the clinical range (SDQ-E ≥6; UE-number ≥1); SDQ: Strengths and Difficulties Questionnaire (Goodman, 2001); ESS: Emotional Symptoms Scale; UE = unusual experience; UED = unusual experience with distress or adverse impact; OR: Odds Ratio; CI: confidence interval. p-values from McNemar Tests.*

**Table 5:** Demographics of followed-up participants and assessment scores at follow-up.

| Variable | Trial baseline *n = 48* | 1-month post-therapy *n=29* | *Baseline to 1-month post-therapy n=29* | 1-4 year FU *n=16* | *Baseline/1-month post-therapy to 1-4 year FU, n=13* |
|---|---|---|---|---|---|
| | **Mean (SD)** | **Mean (SD)** | ***ES (95% CI)*** | **Mean (SD)** | ***ES (95% CI)*** |
| **Age (years)** | 11.7 (2.1)[1] | 11.4 (2.1) | - | 11.5 (2.0)[6] | - |
| **IQ (BPVS)** | 87.0 (16.5) | 88.1 (13.8) | - | 90.2 (13.8)[6] | - |
| **SDQ-ESS** | 7.3 (1.2) | 5.2 (2.0) | *1.2 (0.6 to 1.8)*** | 5.4 (2.8) | *1.1 (-0.0 to 2.2)*/ -0.1 (-0.5 to 0.3), NS* |
| **UE-frequency** | 8.1 (5.1) | 3.3 (5.0) | *0.8 (0.4 to 1.2)*** | 4.4 (4.8) | *0.7 (0.1 to 1.3)*/ 0.04 (-0.6 to 0.7), NS* |
| **UE-D&I** | 10.9 (8.2) | 3.5 (5.3) | *1.0 (0.5 to 1.5)*** | 6.2 (5.7) | *0.5 (-0.1 to 1.1), NS/ -0.4 (-1.2 to 0.4), NS* |
| **UED-number** | 3.8 (2.1) | 1.4 (2.1) | *1.0 (0.5 to 1.5)*** | 2.6 (2.3) | *0.5 (-0.0 to 1.0)*/ -0.4 (-1.0 to 0.2), NS* |
| **UE-number** | 4.4 (2.2) | 2.0 (2.4) | *1.1 (0.6 to 1.6)*** | 3.7 (2.4) | *0.3 (-0.2 to 0.8), NS/ -0.5 (-1.1 to 0.1), NS* |
| **UED-severity** | 23.8 (16.0) | 8.1 (13.1) | *1.0 (0.5 to 1.5)*** | 13.4 (12.8) | *0.6* (-0.0 to 1.2)/ -0.5 (-1.3 to 0.3), NS* |
| **Depression** | 12.0 (6.0)[2] | 9.0 (7.1)[3] | *0.3 (-0.1 to 0.7), NS* | - | - |
| **Anxiety** | 45.9 (17.5) | 30.7 (18.3)[3] | *0.6 (0.2 to 1.0)*** | - | - |
| **SDQ-Total** | 20.7 (5.0) | 16.2 (5.3) | *0.6 (0.2 to 1.0)*** | 16.6 (8.0) | *0.3 (-0.4 to 1.0), NS/ 0.2 (-0.2 to 0.6)), NS* |
| | **% (n) (95% CI)** | **% (n) (95% CI)** | ***McNemar Test*** | **% (n) (95% CI)** | ***McNemar Test*** |
| **Gender** (F:M) | 53%:47% (26:23)[1] | 52%:48% (15:14) | - | 53%:47% (10:9)[6] | - |
| **Ethnicity** BME/non-BME | 46%:54% (22:26) | 45%:55% (13/16) | - | 37%/63% (7:12)[6] | - |
| **SCREEN+ve** | 100% (48) | 34% (10) (25% to 43%) | *p=0.002* | 38% (6) (25% to 43%) | *p=0.008/NS* |
| **SDQ-ESS** Clinical range | 100% (48) | 48% (14) (39% to 57%) | *p<0.001* | 38% (6) (26% to 50%) | *p=0.008, NS* |
| **UE** Present | 100% (48) | 69% (20) (60% to 78%) | *p=0.004* | 88% (14) (80% to 96%) | *NS, NS* |
| **UED** Present | 98% (47) (96% to 100%) | 52% (15) (43% to 61%) | *p<0.001* | 81% (13) (71% to 91%) | *NS, NS* |
| **Family/ Parental MI** | 73%/43% (36/21)[1] | 79%/45% (23/13) | - | 84%/53% (16/10)[6] | - |
| Speech/motor delay/problem | 37% (13)[4] | 21% (6)[5] | - | 21% (4)[7] | - |

*Key: FU: follow-up; SD: standard deviation; df: degrees of freedom; IQ: Intelligence Quotient; BPVS = British Picture Vocabulary Scale (Dunn et al., 1997). SDQ: Strengths and Difficulties Questionnaire (Goodman, 2001); ESS: Emotional Symptoms Scale; UE = unusual experience; UE-D&I: Distress and adverse impact associated with UE; UED = unusual experience with distress or adverse impact; BME: Black or minority ethnic; SCREEN+ve: scoring in the clinical range (SDQ-ESS ≥6; UE-number ≥1); MI: Self-reported mental illness history; 1n=additional TAU participant (n=49); 2n=46; 3n=28; 4n=35; 5n=17; 6n=19 (includes 3 non-treatment cases); 7n=15. ES: effect size, Cohen's d, derived from pre-post change mean differences over the common SD; *p<0.05; **p<0.01; ***p<0.001 – significance levels derived from within group paired t-test of pre-post scores.*

Appendix A: CONSORT checklist

| Section/Topic | Item No | Checklist item | Reported on page No |
|---|---|---|---|
| **Title and abstract** | | | |
| | 1a | Identification as a pilot or feasibility randomised trial in the title | 1 |
| | 1b | Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials) | 3 |
| **Introduction** | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial | 5-6 |
| | 2b | Specific objectives or research questions for pilot trial | 6 |
| **Methods** | | | |
| Trial design | 3a | Description of pilot trial design (such as parallel, factorial) including allocation ratio | 9-10 |
| | 3b | Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons | N/A |
| Participants | 4a | Eligibility criteria for participants | 6, 9-10 |
| | 4b | Settings and locations where the data were collected | 6 |
| | 4c | How participants were identified and consented | 6, 10 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 11 |

| | | | |
|---|---|---|---|
| Outcomes | 6a | Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed | 9-10 |
| | 6b | Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons | N/A |
| | 6c | If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial | 9-10 |
| Sample size | 7a | Rationale for numbers in the pilot trial | 9 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | N/A |
| Randomisation: | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | 9 |
| | 8b | Type of randomisation(s); details of any restriction (such as blocking and block size) | 9 |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | N/A |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | 9 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | N/A |
| | 11b | If relevant, description of the similarity of interventions | 9-11 |
| Statistical methods | 12 | Methods used to address each pilot trial objective whether qualitative or quantitative | 12-14 |

| | | | |
|---|---|---|---|
| **Results** | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective | 14,33 |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | 14, 33 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | 14 |
| | 14b | Why the pilot trial ended or was stopped | N/A |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | 34 |
| Numbers analysed | 16 | For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group | 14-20, 35-37 |
| Outcomes and estimation | 17 | For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any<br>estimates. If relevant, these results should be by randomised group | 14-20, 35-37 |
| Ancillary analyses | 18 | Results of any other analyses performed that could be used to inform the future definitive trial | 14-20 |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | 16-17 |
| | 19a | If relevant, other important unintended consequences | 16-17 |
| **Discussion** | | | |
| Limitations | 20 | Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility | 20-23 |
| Generalisability | 21 | Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies | 20-23 |

| | | | |
|---|---|---|---|
| Interpretation | 22 | Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and<br><br>considering other relevant evidence | 20-23 |
| | 22a | Implications for progression from pilot to future definitive trial, including any proposed amendments | 20-23 |
| **Other information** | | | |
| Registration | 23 | Registration number for pilot trial and name of trial registry | 5 |
| Protocol | 24 | Where the pilot trial protocol can be accessed, if available | 10 |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | 24 |
| | 26 | Ethical approval or approval by research review committee, confirmed with reference number | 10 |

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.